DEPARTMENT OF HEALTH AND HUMAN SERVICES.

Food and Drug Administration

[Docket No. **2003D–0537]**

Guidance for Industry and FDA Staff; User Fees and Refunds for Premarket Notification Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "User Fees and Refunds for Premarket Notification Submissions (510(k)s)." This guidance describes the user fees and refunds associated with the 510(k) program. The guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "User Fees and Refunds for Premarket Notification Submissions (510(k)s)" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://*

www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For device issues: Heather *S.* Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190 ext. 143.

For biologics issues: Leonard Wilson, Center for Biologics Evaluation and Review (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION':

I. Background

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107–250, amends the Federal Food, Drug, and Cosmetic Act (the act) to allow FDA to collect user fees for certain premarket reviews. The new law also permits refunds under certain circumstances. The guidance outlines the user fees due with 510(k) submissions and the circumstances in which FDA plans to provide refunds.

This guidance document is immediately in effect because the agency is already collecting user fees under the new law and wants to provide guidance to its stakeholders. On February 4, 2003, FDA published a notice in the **Federal Register** (68 FR 5643) to establish a public docket (02N–0534), so that we could share information on the implementation of MDUFMA and to provide interested persons an opportunity to share their views. On December 3, 2003, the agency held an open public meeting to update its stakeholders on its progress in implementing the new law, discuss some of MDUFMA's more

challenging provisions, and obtain input from interested parties. Since establishing the docket over a year ago, the agency has received quite a few comments from its stakeholders on a number of MDUFMA provisions, including the application and refund of user fees. During the drafting of this guidance, the agency specifically solicited comments to the docket in recognition of the interest in this issue. The agency has considered all comments received to date and believes that the approach presented below is a fair application of its refund policy. FDA will accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on user fees and refunds for 510(k)s. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive "User Fees and Refunds for Premarket Notification Submissions (510(k)s)" by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1511) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the

CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB No. 0910–0120).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the

docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/21/04
May 21, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S